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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,330	03/07/2007	Thomas A. Osborne	8627/1247 (PA-5573-PCT/US)	3188
48004 7590 11/24/2010 BRINKS HOFER GILSON & LIONE/INDY/COOK BRINKS HOFER GILSON & LIONE CAPITAL CENTER, SUITE 1100 201 NORTH ILLINOIS STREET INDIANAPOLIS, IN 46204-4220			EXAMINER PIERY, MICHAEL T	
			ART UNIT 1742	PAPER NUMBER
			MAIL DATE 11/24/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,330	Applicant(s) OSBORNE, THOMAS A.	
	Examiner MICHAEL T. PIERY	Art Unit 1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8,10 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8,10 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 2, 4, 6-8, 10, 21-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste (US 6,508,806) in view of van Muiden (EP 0662385).

Regarding claim 1, Hoste teaches a method of making an introducer sheath including positioning a coil over a mandrel (column 4, lines 49-60), positioning a second reinforcing member over the coil where the second reinforcing member has a braid configuration (figure 4), positioning a heat shrink tube over the assembly and heating the material cause the heat shrink material to shrink (column 5, line 54-column 6, line 3). Hoste does not explicitly teach positioning two sleeves with striped extrusions on the coil. Van Muiden, however, teaches it is known to for reinforcing members by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a braid-like configuration (column 4, lines 25-44). It would have

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been obvious to one of ordinary skill in the art at the time of the invention to substitute the braid of Hoste with the two helical striped sleeves forming a braid of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste (column 2, lines 52-55). The examiner interprets that the shrink jacket process of Hoste when modified by van Muiden would form an assembly where the sleeves are melted together to obtain a braid configuration. Van Muiden further teaches it is desirable for the shaped bands of material to achieve a good bond (column 4, lines 32-35).

Regarding claim 2, Hoste does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the sleeves have a striped helical pattern (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 4, Hoste does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the stripes extend from the outer surface to the inner surface of both sleeves (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste .

Regarding claim 6, Hoste does not explicitly teach sleeves are coextruded with stripes. However, van Muiden teaches the sleeves are co-extruded with the stripes (column 2, lines 43-

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47). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claims 7 and 8, Hoste teaches it is known to place an inner liner material over a mandrel then place a coil over the inner liner then bond a sleeve to the coil and heating the layers in a shrink tube (column 4, lines 36-48).

Regarding claim 10, Hoste does not explicitly teach a sleeve comprises two segments. However, van Muiden teaches forming a sleeve with two sleeve segments, where one has a higher durometer than the other (column 1, lines 25-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hoste to include multiple segments because the multiple segments allow for variation in properties, such as stiffness, along the length of the catheter.

Regarding claim 21, Hoste teaches a method of making an introducer sheath including positioning a liner over a mandrel (figure 2, #22), positioning a coil over the liner (column 4, lines 49-60), positioning a second reinforcing member over the coil where the second reinforcing member has a braid configuration (figure 4), positioning a heat shrink tube over the assembly and heating the material cause the heat shrink material to shrink (column 5, line 54-column 6, line 3). Hoste does not explicitly teach positioning two sleeves with striped extrusions on the coil. Van Muiden, however, teaches it is known to for reinforcing members by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a braid-like

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configuration (column 4, lines 25-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the braid of Hoste with the two helical striped sleeves forming a braid of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste (column 2, lines 52-55). The examiner interprets that the shrink jacket process of Hoste when modified by van Muiden would form an assembly where the sleeves are melted together to obtain a braid configuration. Van Muiden further teaches it is desirable for the shaped bands of material to achieve a good bond (column 4, lines 32-35).

Regarding claim 22, Hoste teaches removing the mandrel and heat shrinking sleeve (column 4, lines 45-48).

Regarding claim 23, Hoste does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the stripes extend from the outer surface to the inner surface of both sleeves (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 24, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches two sleeves with helical patterns. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

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Regarding claim 25, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches the sleeves are coextruded with the striped extrusion (column 4, lines 25-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claims 26 and 27, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches it is known to vary the composition and pattern of extrudates in order to vary the stiffness and physical properties of the sheath. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 28, Hoste teaches the sleeve is formed by polyamide material (column 5, lines 54-59).

Regarding claim 29, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches it is known to form sleeves of polyamide material with a higher durometer stripe (column 5, lines 10-15). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

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Regarding claim 30, Hoste does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches forming the sleeves by a stripe extrusion process (column 4, lines 1-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Hoste with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Hoste.

Regarding claim 33, Hoste does not explicitly teach the claimed thickness range. It would have been obvious, however, to one of ordinary skill in the art at the time of the invention to modify the process of Hoste to use a wall thickness of 0.010 inch because it has been held that where the general conditions of a claim are disclosed, finding the optimum workable range is *prima facie* obvious (MPEP 2144).

3. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste (US 6,508,806) in view of van Muiden (EP 0662385), as applied above to claims 21 and 27, and further in view of Garabedian et al. (US 6,171,295).\

The modified Hoste reference teaches the method of claims 21 and 27, as applied above.

Regarding claims 31 and 32, Hoste does not explicitly teach the lower durometer sleeve includes a radiopaque material. Garabedian, however, teaches it is known to form catheters using radiopaque material (column 1, lines 29-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of Hoste to use radiopaque material because the material allows the physician to monitor the movement of the catheter (column 1, lines 31-40).

Response to Arguments

Applicant's arguments filed September 14, 2010 have been fully considered but they are not persuasive.

Applicant argues that the combined cited references do not teach a thin-walled catheter. The examiner disagrees. Both references teach a thin walled catheter is desirable (column 2, lines 21-29 of Hoste; column 1, lines 16-19 of van Muiden). Further, there is no indication that substituting the braid of van Muiden for the braid of Hoste would increase the thickness to a point where the catheter would be undesirable.

Applicant argues that there is no teaching or suggestion of a heat shrinking step. The examiner disagrees. Hoste teaches heat shrinking steps (column 5, line 54-column 6, line 3).

Applicant argues that there is no teaching or suggestion of a manner by which the structure of van Muiden could be combined with a coiled reinforcement. Hoste teaches applying a braid over the coil and one in the art would readily recognize that the braid of van Muiden would be applied over the coil.

Applicant argues that Hoste did not see fit to use the teachings of van Muiden. For a showing of obviousness, it is not necessary to demonstrate that the prior art used the combination, rather it is necessary to show that one of ordinary skill in the art at the time of the invention would have found the combination to be obvious.

Applicant argues that by maintaining two outer layers, van Muiden teaches away from the desirability of providing a sheath having as small a wall thickness as possible. The examiner disagrees. Hoste's teaching is not only that the catheter has a small wall thickness but the catheter also has certain structural properties (column 2, lines 54-56). Hoste's teaching is to

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optimize the wall thickness in order to obtain the certain structural properties for the end use of the catheter, not just to find the smallest possible wall thickness. The two layers of van Muiden are not a teaching away from Hoste because van Muiden has found the optimal wall thickness given the desired properties of the catheter. Further, when the heat shrinking step of Hoste is applied to the braided coil of van Muiden, the two layers become one layer, thus minimizing the thickness.

Applicant argues that Hoste does not teach heating the striped sleeves. Hoste teaches heating the tube after the braid has been applied. When the braid of van Muiden is substituted for the braid of Hoste, the subsequent heat shrinking step would melt the layers together.

Applicant argues that van Muiden does not teach melting the striped layers together. Hoste teaches heat shrinking the catheter assembly. When the braid of van Muiden is substituted for the braid of Hoste, the subsequent heat shrinking step would melt the layers together. Further, van Muiden suggests the layers should possess a "good bond" (column 4, lines 34-35). The two layers melted together would possess this desirable "good bond."

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. PIERY whose telephone number is (571)270-5047. The examiner can normally be reached on M-Th 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael T Piery/
Examiner, Art Unit 1742

/Monica A Huson/
Primary Examiner, Art Unit 1742